Training Course in Sexual and Reproductive Health Research 2013

Module: Principles and Practice of Sexually Transmitted Infections Prevention and Care

STI case management

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Session outline

- STI case management
- STI syndromic case management
  - Algorithm development
  - Implementation
  - Algorithm evaluation
- STI laboratory diagnosis
- Screening

Objectives of an STI programme

- to interrupt the transmission of sexually transmitted infections
- to prevent development of disease complications and sequelae
- to reduce the risk of HIV infections

Objectives of STI case management

- to provide appropriate antimicrobial therapy in order to:
  - obtain cure of infection
  - decrease infectiousness
- to limit or prevent high risk behaviour
- to ensure that sexual partners are treated in order to interrupt the chain of transmission

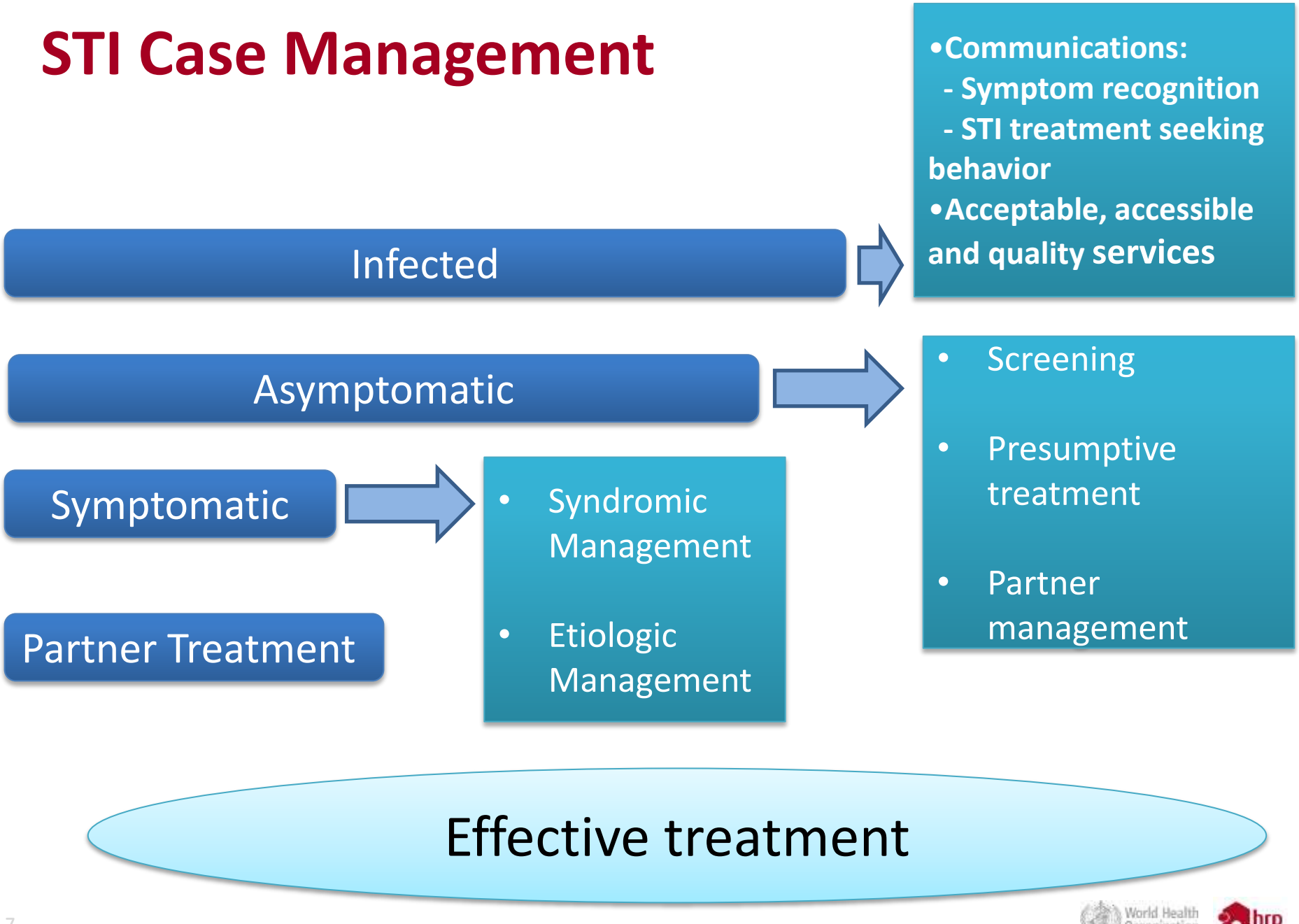
STI case management: Requirements

- Accurate diagnosis
- Treat at first encounter
- Rapid cure with effective drugs
- Simple
- Integrated approach
- Condom promotion
- Education/Counselling
- Partner notification

Components of Comprehensive STI case management

- History taking (symptoms and risk assessment)
- Examination (signs)
- Treatment
  - Patient and sexual partners
- Counselling for STIs and HIV testing
- Condom promotion

STI Case Management



Diagnostic approaches

	Disadvantages
• clinical	• Low sensitivity and specificity • Mixed infections cannot be detected
• laboratory	• Simple tests not available • Cost: existing rapid tests expensive (except for syphilis) • Delay: results are not readily available
• syndromic	• Cost of over-treatment • Side-effects of antimicrobials treatment

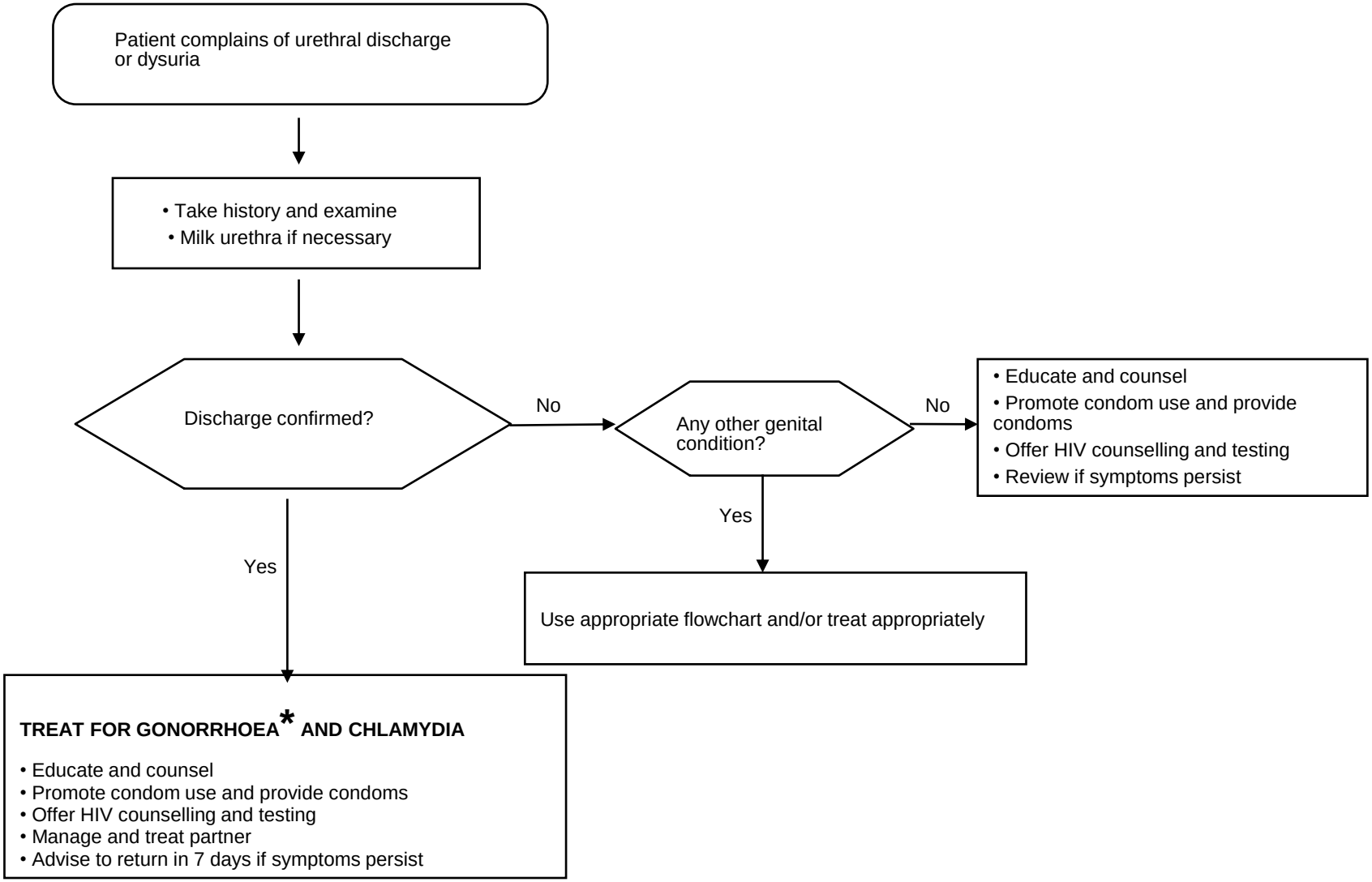
Operating principles (Factors that influence patients' choice of health facility)

- Accessible
  - Location
  - Convenient opening hours
  - Affordable
- Acceptable
  - Non- stigmatizing
  - Non- judgmental staff
  - Linked to other services
- Confidential
- Quality of services
  - Efficiency of service delivery
  - Effective services / therapy
  - Available drugs and other resources
  - In line with standard guidelines
  - Informed consent

STI syndromic case management

- Syndromic diagnosis:
  - Identification of consistent group of symptoms and easily recognized signs (syndromes)
- Syndromic treatment:
  - Treat the main organisms responsible for causing the syndrome
- Through a series of flowcharts:
  - guides the health-care worker through the correct identification and treatment of an STI-associated syndrome
  - offers a package of comprehensive care from history taking, examination, to counselling/education on risk reduction and partner notification and treatment

Urethral discharge



*If microscopy is available, do Gram stain smear of urethral exudates. If no intra-cellular Gram-negative diplococci are seen, treatment for chlamydial infection only may be considered.

Test-of-Cure for *N. gonorrhoeae*

ASYMPTOMATIC but

- Test-of-Cure positive for *N. gonorrhoeae* by Gram stain, culture or NAATs

OR

- sex partner of person with cephalosporin-resistant *N. gonorrhoeae*

↓

Take history and examine to exclude other infections or conditions

↓

MANAGE AS CEPHALOSPORIN-RESISTANT *N. GONORRHOEAE*

- Collect specimen for microscopy, culture and susceptibility tests or NAATs and genotyping (subject to availability of resources and laboratory capacity)
- Treat immediately with higher dose of ceftriaxone IM (500mg-1gm)*
- REVIEW AFTER 72 HOURS OR
- REVIEW AFTER 7 DAYS IF ONLY NAAT TESTING IS AVAILABLE

↓

PERFORM TEST-OF-CURE
Collect specimen for bacteriological culture or NAATs and genotyping (if possible)

↓

Test-of-Cure negative?

Yes →

- Educate and counsel
- Promote/provide condoms
- Ensure treatment of sex partner(s)

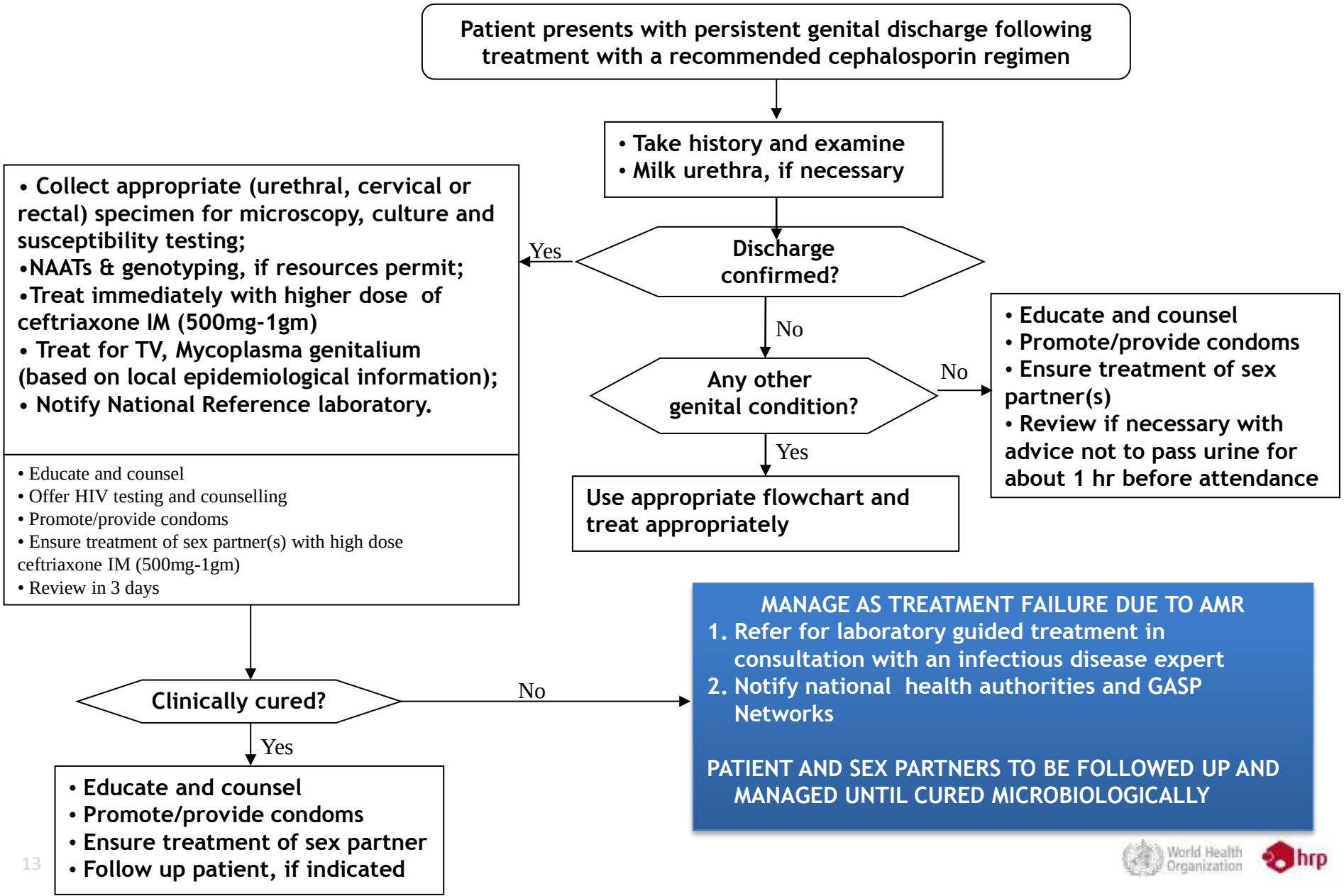
No →

MANAGE AS TREATMENT FAILURE

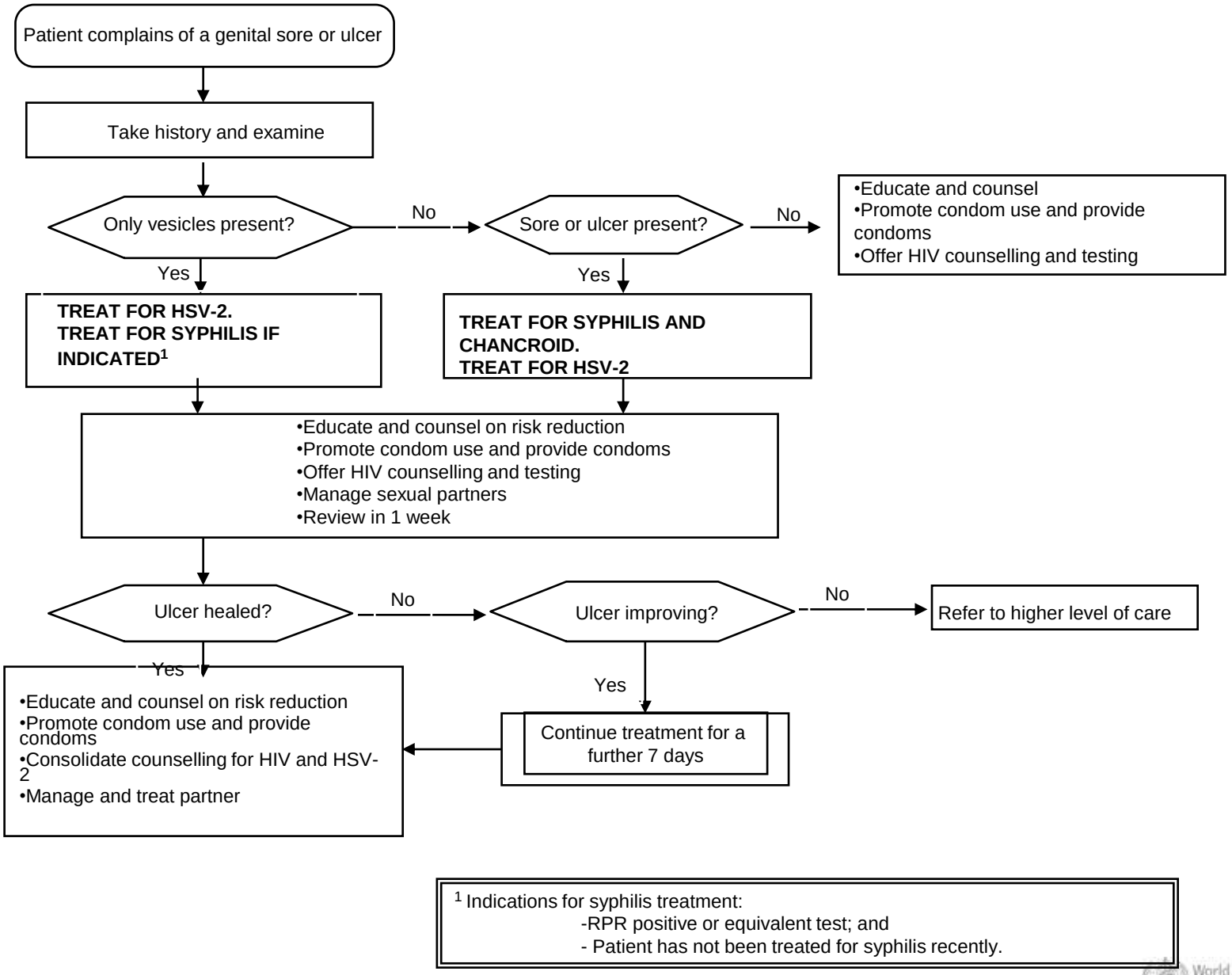
1. Laboratory-guided treatment in consultation with an infectious disease expert
2. Dual therapy (2gm Azithromycin + Gentamicin 240mg or Spectinomycin 2gm) OR
3. Either Gentamicin 240mg or Spectinomycin 2gm)
4. Notify national health authorities and GASP Networks
5. Review and perform another test-of-cure
6. FOLLOW UP UNTIL CURED MICROBIOLOGICALLY

Flowchart for the management of cephalosporin treatment failure for urogenital infections – symptomatic patients

N.B. This flowchart assumes that the patient has received and taken effective therapy for gonorrhoea and chlamydia prior to this consultation OR Chlamydial infection has been reliably excluded by appropriate laboratory tests



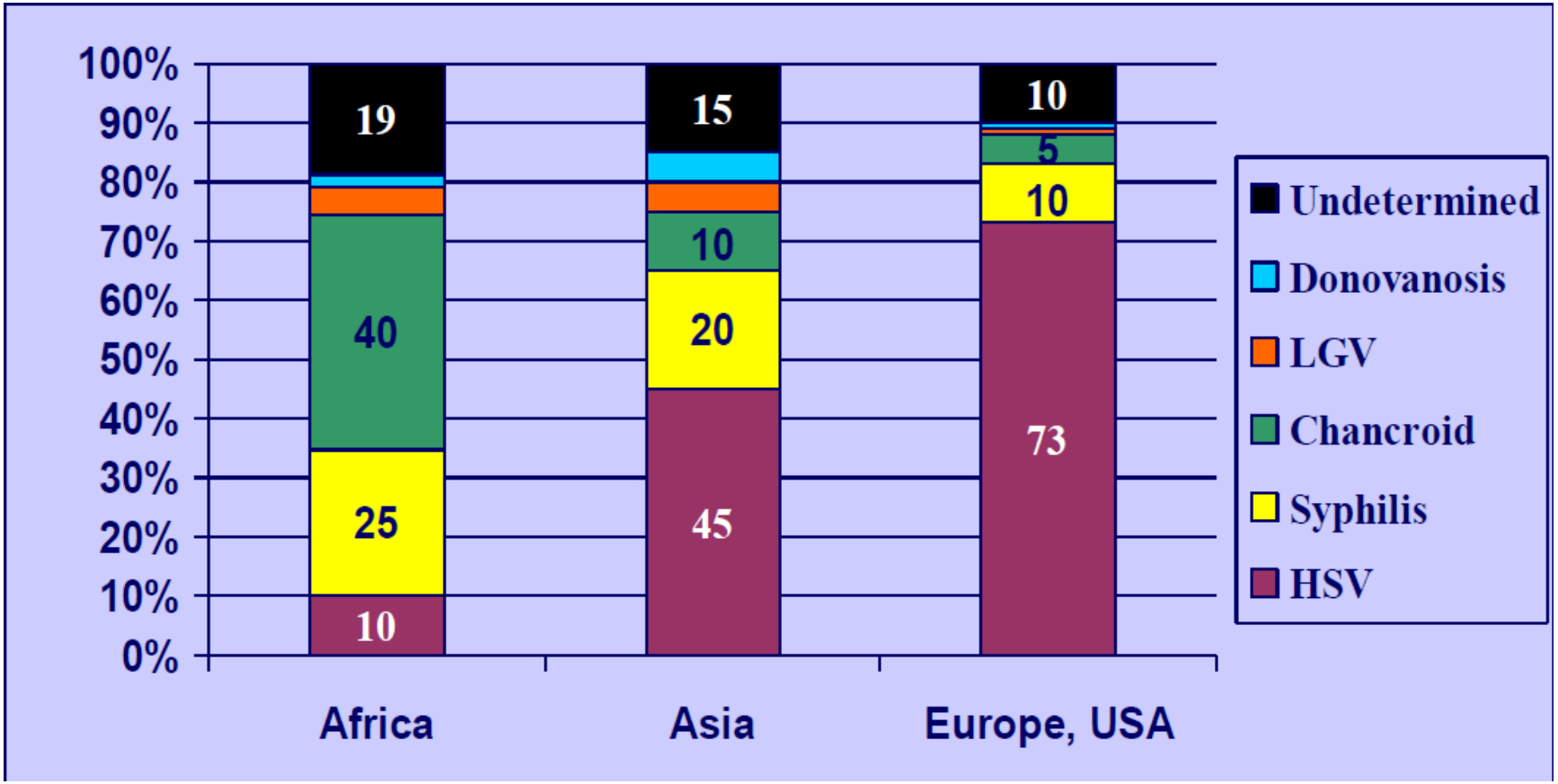
Genital ulcer disease



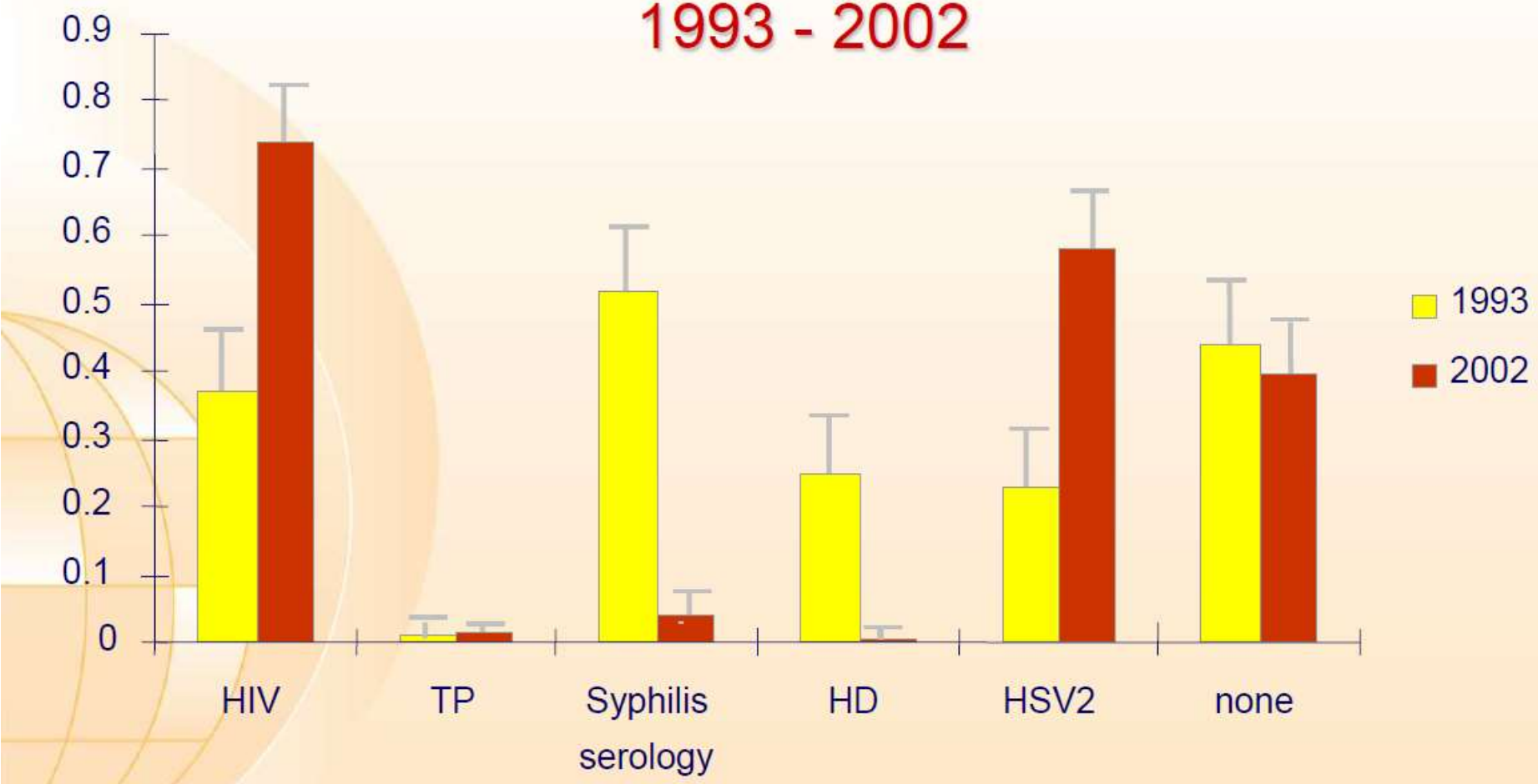
[1] Indications for syphilis treatment:
-RPR positive or equivalent test; and
- Patient has not been treated for syphilis recently.

Figure 3

Agents causing genital ulcer disease (GUD) by region until 1990's



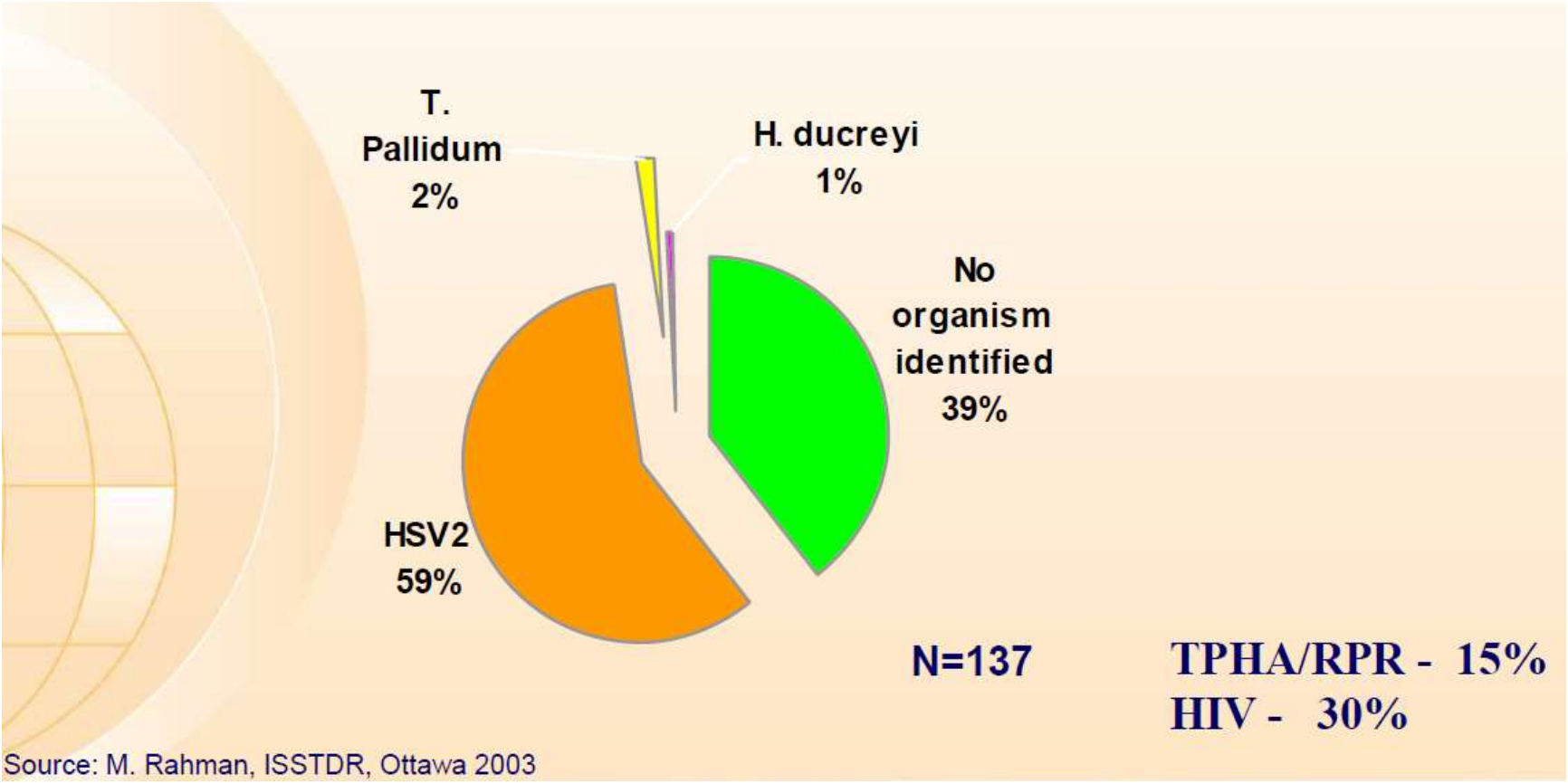
Botswana
Changes in the aetiology of GUD
1993 - 2002



*In 1993 a study was done by the National AIDS Control Program in Botswana in collaboration with the STD Research Unit, South African Institute for Medical Research, Johannesburg among 108 GUD patients.

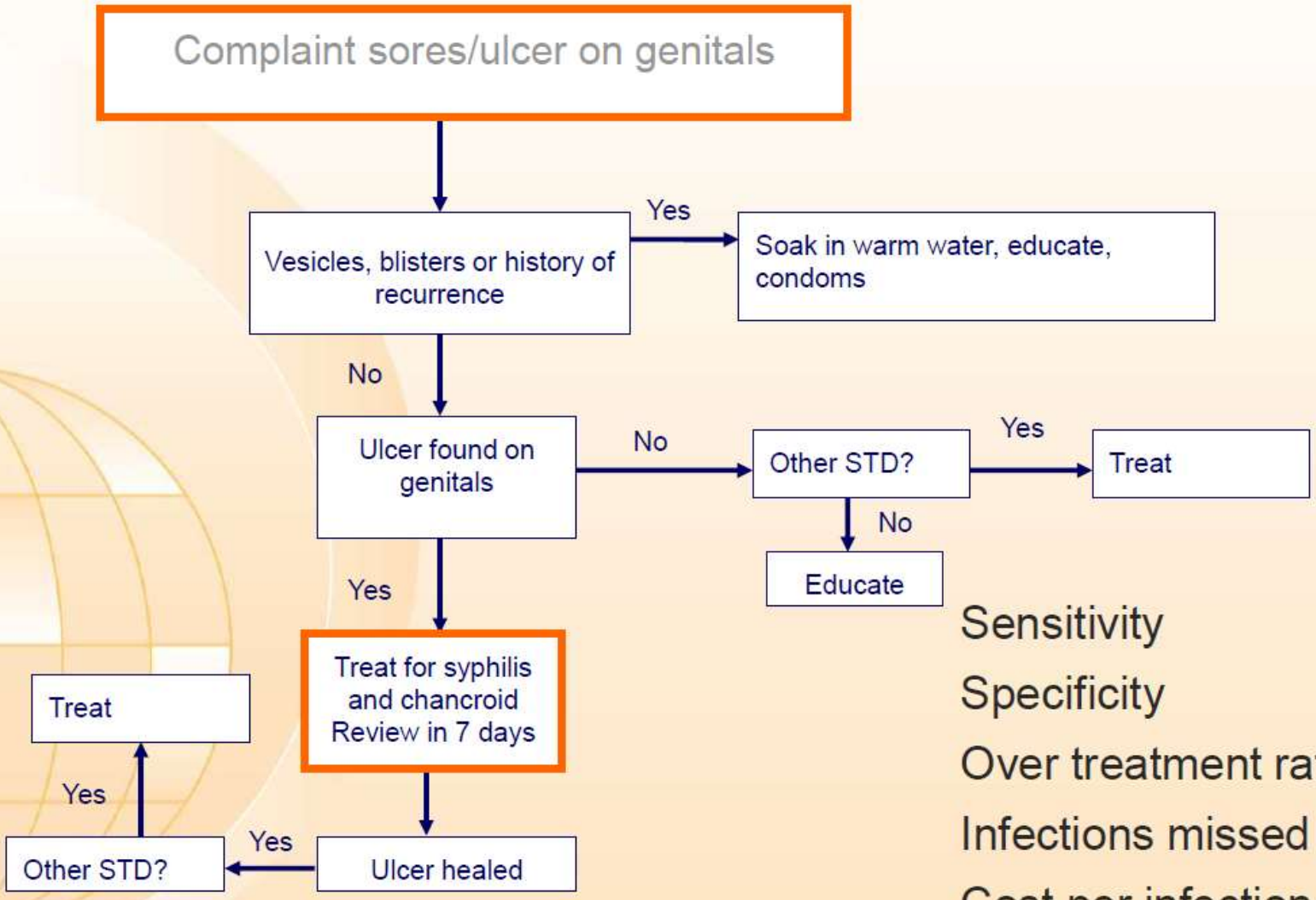
Source: M. Rahman, ISSTDR, Ottawa 2003

Botswana: Aetiology of genital ulcer disease 2002



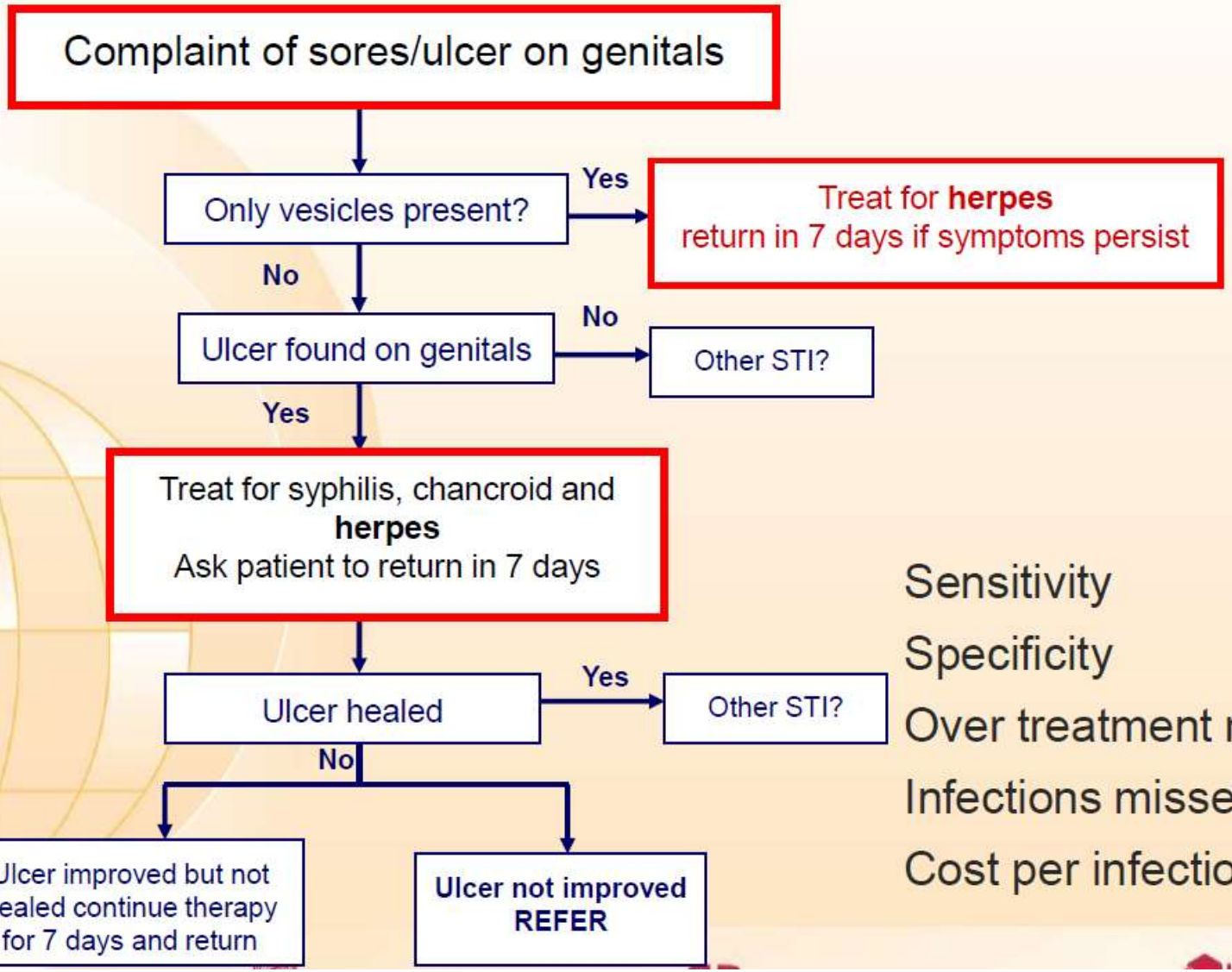
Source: M. Rahman, ISSTDR, Ottawa 2003

Current genital ulcer algorithm in Botswana



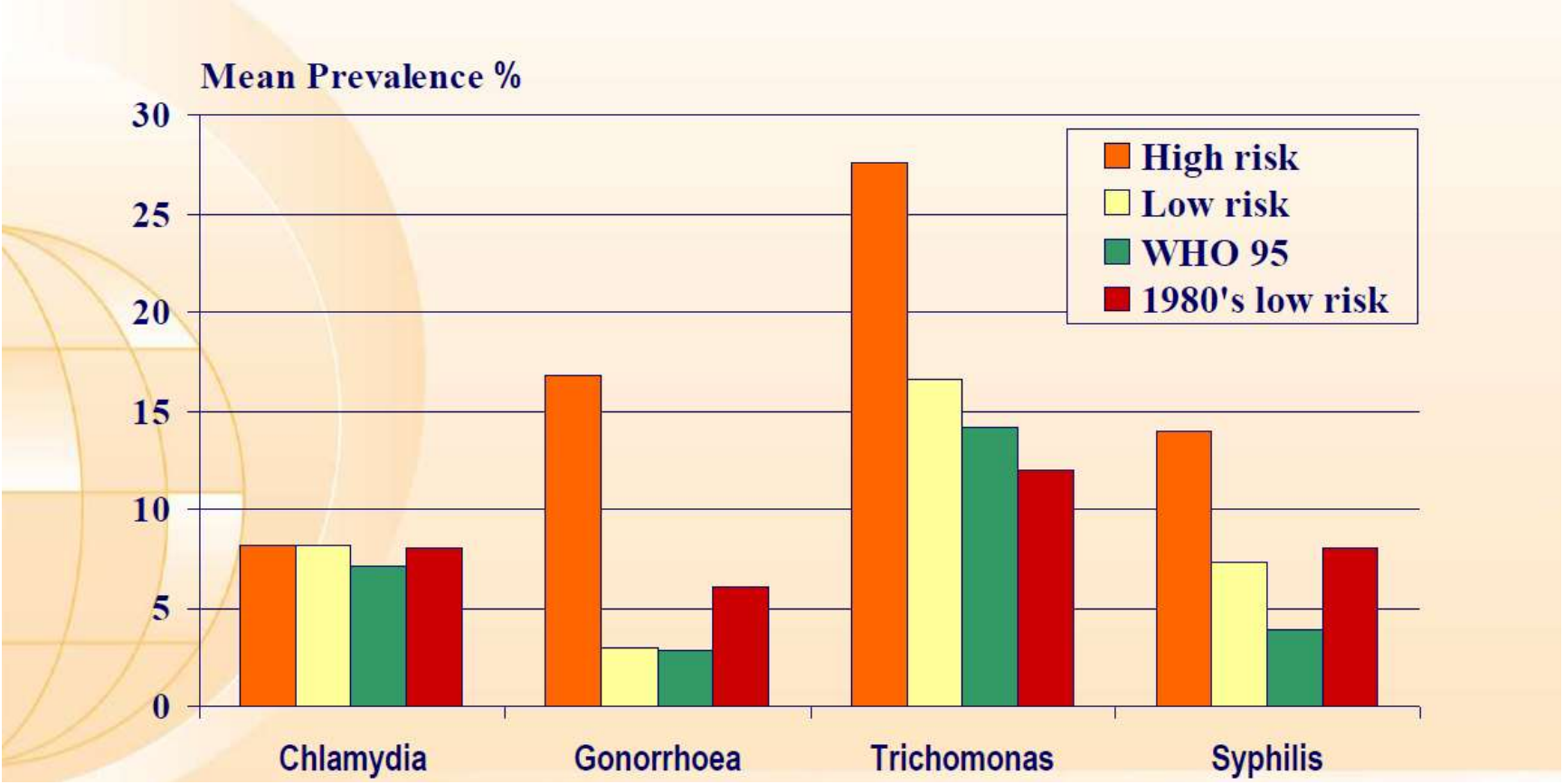
Sensitivity	33%
Specificity	45%
Over treatment rate	99%
Infections missed	67%
Cost per infection Tx.	$88.0

Piloted genital ulcer algorithm in Botswana



Sensitivity	99%
Specificity	13%
Over treatment rate	36%
Infections missed	1%
Cost per infection Tx.	$4.5

Prevalence of selected STIs among female populations in Africa in the 1980's and 1990's



Vaginal discharge syndrome

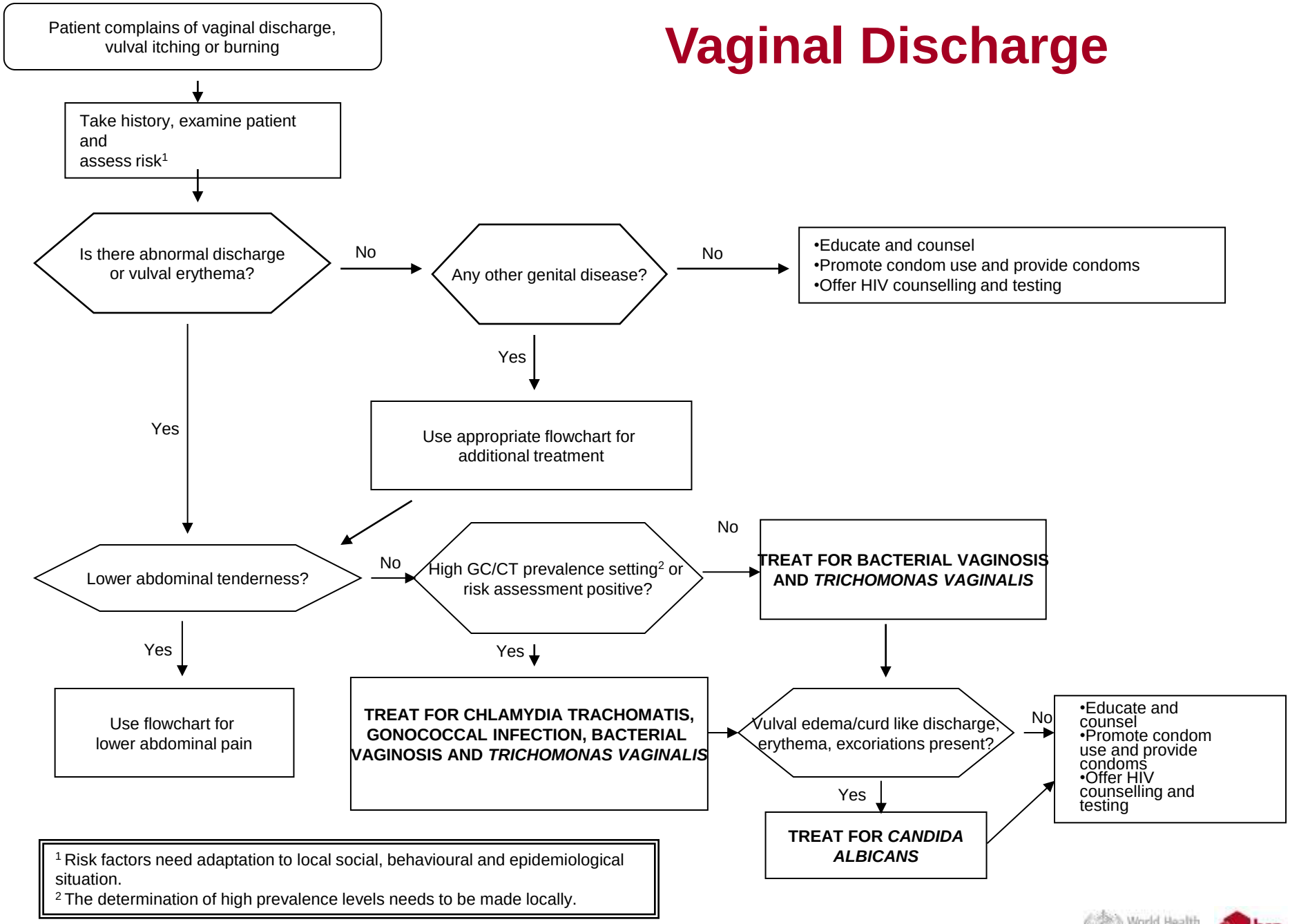
VAGINITIS

- Most common causes
- Easy to diagnose
  - Lab tests
  - Clinically
- Serious complications (?)
  - Adverse outcome of Pregnancy
  - Endometritis, PID
  - BV and HIV

CERVICITIS

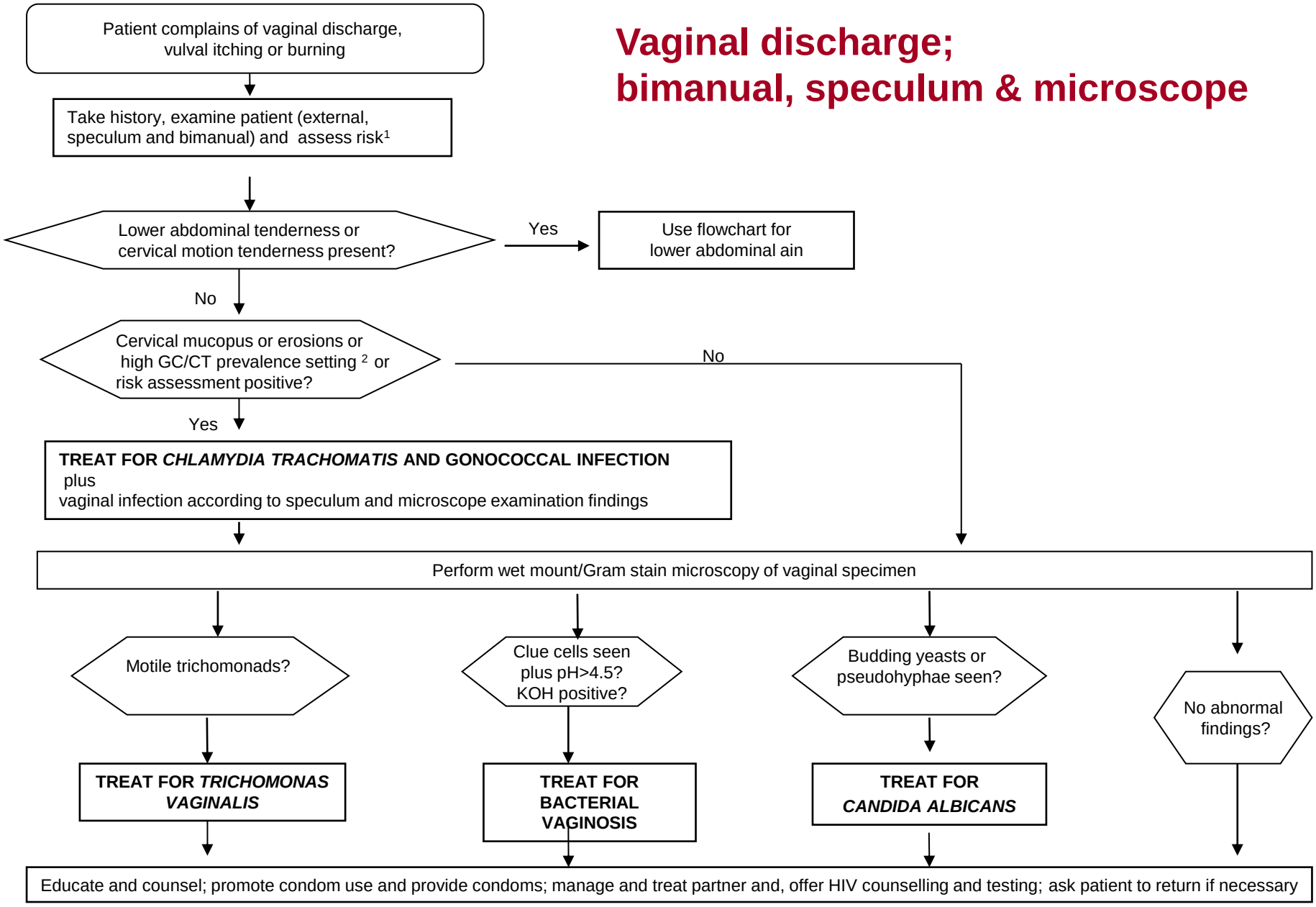
- uncommon cause
- Not easy to diagnose
  - No simple tests
- Complications are severe
  - PID
  - Ectopic pregnancy
  - Infertility

Vaginal Discharge



[1] Risk factors need adaptation to local social, behavioural and epidemiological situation.
[2] The determination of high prevalence levels needs to be made locally.

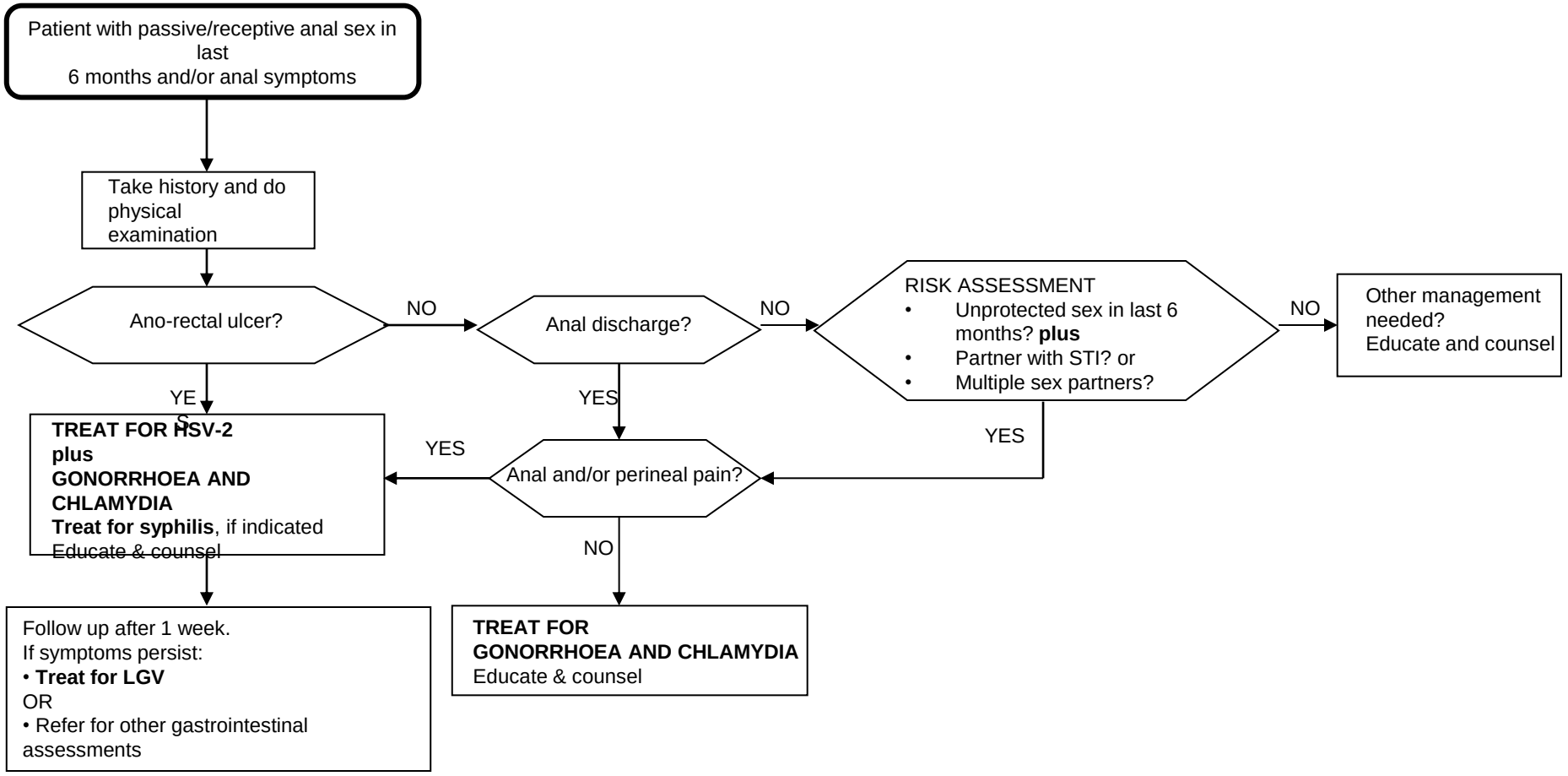
Vaginal discharge; bimanual, speculum & microscope



[1]Risk factors need adaptation to local social, behavioural and epidemiological situation.
[2]The determination of high prevalence levels needs to be made locally.

MANAGEMENT ALGORITHM FOR ANO-RECTAL INFECTIONS

Due to its low sensitivity, microscopy is not recommended in the management of ano-rectal infections.



Implementation: Pre- requisite information

- Prevalence of STIs
- STI treatment-seeking behaviour
- Treatment practices & counselling (PI6 & PI7)
- Level of (and capacity for) training of
- implementers
- Drug policy, ordering and distribution system
- Stakeholders involvement
- Review of literature (need ‘evidence criteria’)

Implementation con't

- Conduct or analyze etiological studies
  - Genital ulcer syndrome
  - Male genital discharge syndrome
  - Female genital discharge (+/- risk-assessment)
  - Resistance patterns
- Assess if there is need to depart from WHO or existing national/regional algorithms
- Adaptation for high/low risk environment
  - high/low prevalence area
  - high risk/low risk populations

Implementation con't

- Determine the role of the laboratory
  - for case management (and monitoring as 'test of cure')
  - for screening and case finding
  - for supporting research
  - for antimicrobial susceptibility studies
- Determine levels of use/capacity
  - will influence flowchart design & need pre-testing
  - will influence choice of drugs
  - depends on referral patterns

Implementation : drug selection

- Criteria for the choice of drugs (WHO, 2003)
  - efficacy (cure at least 95% of those infected)
  - safety
  - cost
  - compliance and acceptability
  - availability (e.g. at primary health care level)
  - use in pregnancy
  - broad spectrum (can cover co-existing infections)
  - resistance unlikely to occur rapidly

Implementation con't

- Printing and distribution (and translation) of flowcharts
- Training
  - post-service institutional training
  - on-the-job training
  - pre-service training
  - what cadres to train
- Drug procurement and distribution

Implementation: Monitoring and Supervision

- WHAT?
  - clinical outcomes on returnees and non-returnees
  - cured/ improved/ treatment failures
  - referral/ no follow-up
  - *Neisseria gonorrhoeae* susceptibility
  - etiological surveys
  - quality of care (PI6, PI7)
- HOW (universal? sentinel sites? Standardised protocols? consensual workshops)
- WHEN?

Evaluation of algorithms

- Validity : sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV)
- Feasibility: infrastructure, personnel
- Cost: direct and indirect costs, cost/effectiveness
- Acceptability: health care provider, STI patient, programme manager

Validity of an algorithm

- Comparison between:
  - Outcome of algorithm – simultaneous studies, real outcome in field conditions
  - Gold standard diagnosis – laboratory tests

		Gold standard test	
		+	-
Algorithm	+	A: (true positive) Correctly treated	B: (false positive) Over-treated
	–	C: (false positive) Missed infections	D: (true negative) Correctly diagnosed as negative
		Total infected	Total not infected

Sensitivity: A/ A+ C
Specificity: D/ B+D
Positive Predictive Value: A/ A+B
Negative Predictive Value: D/ C+D

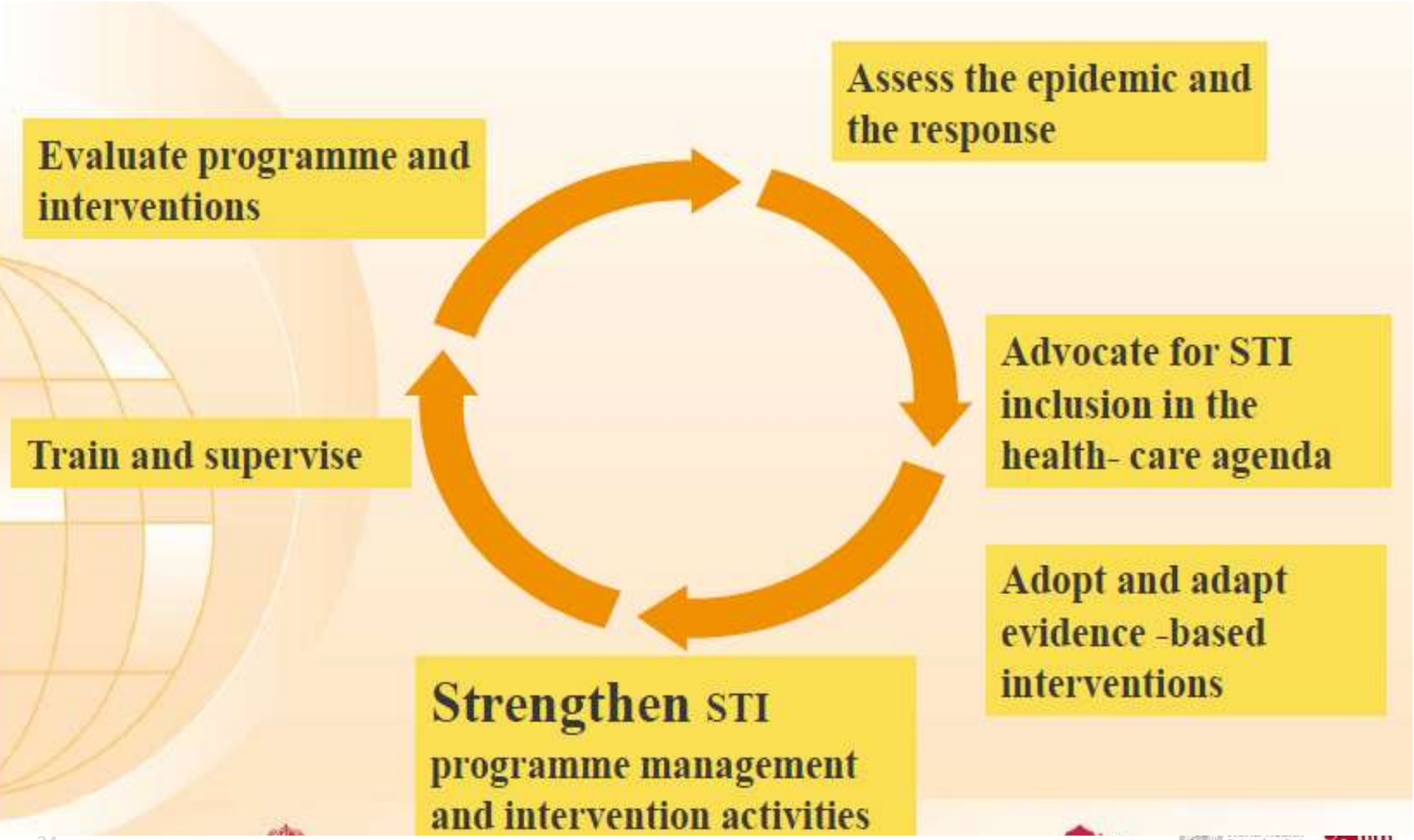
Cost per case cured

$$\frac{\text{Total cost of all diagnoses and treatment}}{\text{Number of cases cured}}$$

Cost per case cured decreases if:

- Prevalence increases
- Specificity of flowchart increases

Implementation Cycle



Screening for STI (Asymptomatic STIs)

- Asymptomatic STIs are major concern

- Population to screen
  - SW (HIV guidelines)
  - MSM/TG (HIV guidelines)
  - Pregnant women
  - FP clients
  - Sexually active adolescents (??)
  - Patients diagnosed with other STIs

- STIs to screen
  - Syphilis
  - Gonorrhoea
  - Chlamydia
  - Trichomonas
  - HIV

Important Considerations:

Which population should be targeted for screening?

What STIs to screen? Which STI to screen when + for one, when HIV+?

When to screen? Re-screening

How to screen?
- What tests including rapid test?
- How frequent?
- What methodology?

What treatment ? E.g. GC+ CT

Screening

Populations	STIs	Laboratory Test	Comments
Sex workers, men having sex with men and transgender	Syphilis	RPR/ TPHA Rapid Test	Pro-active screening
	Gonorrhoea	GC culture NAAT Gram stain (men)	Usually not available in low resource settings
	Chlamydia	NAAT	
	HIV testing	HIV rapid test	Ensure pre and post test counseling

Screening

Populations	STIs	Laboratory Test	Comments
Pregnant women	Syphilis	RPR/ TPHA Rapid Test	First trimester
	Gonorrhoea	GC culture NAAT	(ideal, based on resources)
	Chlamydia	NAAT	
	HIV testing	HIV rapid test	Ensure pre and post test counseling

Screening

Populations	STIs	Laboratory Test	Comments
Adolescent – below 26 years	Syphilis	RPR/ TPHA Rapid Test	Pro-active screening
	Gonorrhoea	GC culture NAAT Gram stain (men)	
	Chlamydia	NAAT	
	HIV testing	HIV rapid test	Ensure pre and post test counseling

Laboratory Diagnosis of STIs

Choosing tests for STIs

(Numerous STIs and large variety of tests)

- Decide on:
  - Which and how many STIs to invest in testing?
  - Who to test?
  - What purpose?
- Prioritize base on the following:
  - Infection prevalence
  - Impact of the infections and complication on individuals and populations
  - Test performance characteristics
  - Cost of the tests
  - Reasons for testing

Factor influencing choice of the test

- Test specific consideration
  - Performance (sensitivity, specificity, predictive vale)
  - Specimen collection and transport requirements
  - Prevalence
  - Associated morbidity
  - Resources (financial, personal, infrastructure)
  - Relative importance
- Purpose of testing
  - Surveillance
  - Quality assurance
  - Evaluation of syndromic diagnosis
  - Diagnosis
  - Screening
  - Antimicrobial susceptibility testing

Laboratory test for syphilis at different level of care

Disease	Laboratory test	Sensitivity	Specificity	P	S	T
Syphilis	Dark Field Microscopy	85-95	100	-	-	+
	VDRL	71-100	79-98	+	+	+
	RPR cards	73-100	79-98	+	+	+
	FTA-ABS	85-100	95-100	-	-	+
	TPPA / TPHA	70-100	96-100	-	+	+
	Rapid test – (treponemal test)	70-100	96-100	+	+	+
	Direct FA	90-95	> 98	-	-	-
	PCR	>95	>99	-	-	-

Level of care: P= primary ; S= secondary; T = tertiary

Partner Management

- Issues:
  - Context specific – index case and gender issues
  - STI discordant partners
  - Partner violence – tools to assess and prevent
  - Increase coverage for partner notification and management

- Approaches:
  - patient referral – contact cards, concurrent patient- partner therapy (CPPT) or bring in your own partner (BYOP)
  - patient delivered partner therapy (PDPT) - evidence of decreased re-infection

    (Studies have shown that provision of medication to partners has shown to be more effective that just providing prescription to the partners)
  - provider initiated